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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,287	10/01/2003	Richard Hochberg	Y03-076US	7077

7590 11/13/2006
Henry D. Coleman
714 Colorado Avenue
Bridgeport, CT 06605-1601

EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,287

Applicant(s)

HOCHBERG, RICHARD

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 13-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/4/06</u> . | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. The rejection of claims 1-6 and 13-38 under 35 USC 103(a) over Van den Broek et al. (US 3,972,906) is maintained.

Applicant argument centers on unexpected and unobvious results. Applicant argues (a) the claimed compounds are inactive in traditional estrogenic assay; (b) a skilled artisan looking to synthesize a series of compounds having estrogenic activity as disclosed by the cited reference would be taught away from the present invention because the present compounds would be seen to be inactive in traditional assays such as that shown in Jelinkova and (c) the reference does not disclose or suggest the present compounds are active in treating diseases as presently claimed. Applicant's argument was considered but not persuasive for the following reasons.

First, in order to overcome a prima facie case of obviousness, applicant has to provide a side-by-side comparison of the claimed compounds and the closest prior art compound showing actual differences in the properties of the prior art compounds versus the instantly claimed compounds. There is no evidence of record to support applicant's argument and, thus, the claimed compounds are prima facie obvious based

Art Unit: 1617

on the teaching of a genus that includes 11 β -alkoxy-methyl estradiol derivatives as discussed in the previous Office Action.

Applicant also argues the reference does not disclose or suggest the present compounds are active in treating diseases as presently claimed. As stated in the previous Office Action, the art teaches utilizing estrogenic compounds in the treatment of each of the disorder recited by the instant claims. In addition, the cited reference teaches the compounds possess estrogenic properties and are useful in the treatment of estrogen-deficiency syndromes (see col. 2, lines 29-53). Therefore, the utilization of the prior art compounds in treatment estrogen-deficiency diseases including those recited by the instant claims would have been obvious to the skilled artisan in the art at the time of the present invention.

Lastly, applicant argues the reference teaches away from the claimed compounds because the present compounds would be seen to be inactive in traditional assays such as that shown in Jelinkova. Again, as stated above, in order to overcome a prima facie case of obviousness, applicant has to provide a showing of actual differences in the properties of the claimed compound(s) and the closest prior art compound(s).

For these reasons and those given in the previous Office Actions, the rejection of claims 1-6 and 13-38 under 35 USC 103(a) over Van den Broek et al. (US 3,972,906) is maintained.


Art Unit: 1617

Telephone Inquiry

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB

November 9, 2006